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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,998	01/25/2002	Mark P. Ohan	270/275US	3516
34055	7590	01/27/2004	EXAMINER	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/056,998

Applicant(s)

OHAN ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1/02;5/03 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicants' IDS, filed 05/13/2002; IDS, filed 01/26/2003; and election, filed 11/13/2003.

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-10, in Paper filed 11/13/2003, is acknowledged. The traversal is on the ground(s) that the inventions I, II, and III are not distinct and restriction must not be made because the composition claimed in claims 1-10 is a subcombination essential to the composition of claims 11-12 or 13-14. The composition of each of the inventions of claims 11-12 and 13-14 is a combination of the subcombination. This is not found persuasive because Inventions I, II and III are unrelated, unlike applicants allegation that they are related as combination and subcombination. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the different inventions have different functions. The composition of invention I does not require the active agent and can be used in food products, while the composition of invention II requires active agent and used in drug delivery, and the composition for invention III used for medical devices and does not require the active agent. Invention I requires mixture of sugar and collagen that is

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irradiated, i.e. the whole mixture is irradiated. Inventions II and III do not require the sugar and the collagen both to be irradiated, only the collagen is irradiated and incorporates the sugar. Invention II further requires a compound that is coated by the composition comprising the irradiated collagen. Thus, the requirements for invention I are not required for any of inventions II and III; i.e. the irradiation of the mixture of sugar and collagen. Furthermore, invention II requires an active agent that is coating by the composition comprising irradiated collagen; and invention III requires a specific structure of a medical device.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Claims 1-10 are included in the prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing as they recite "collagen

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mixture" that reads as a mixture of different types of collagen. Recourse to the specification revealed that the collagen mixture is collagen and appropriate solvent, page 9, line 14 of the present specification. Appropriate correction is requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,292,362 ('362).

US '362 discloses a composition in the form of liquid or gel comprising collagen and sugar such as fructose (col.4, lines 53-68; col.5, lines 9-28, 38-43). The composition is irradiated by ultraviolet irradiation (col.5, lines 56-60). The composition is prepared by mixing the components, agitating the mixture to form solution or gel, then exposure to the irradiation at use (col.13, lines 16-24). The collagen is in the form of solution or hydrated components, and that reads on the collagen mixture because applicants disclosed the collagen mixture as collagen and solvent, page 9, line 14 (col.4, lines 29-30; col.13, lines 1-5).

The limitations of claims 1-4, 6, and 8-10 are met by US 362.

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7. Claims 1-4, 6, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,632,773 ('773).

US '773 discloses a composition in the form of gel comprising collagen and sugar such as sucrose (col.6, lines 48-51; col.7, lines 21-30). The composition is irradiated by gamma or ultraviolet irradiation (col.6, lines 60-66). Example I disclosed the method of mixing the components and exposing the mixture to irradiation. The collagen is in form of solution or gel, and that reads on the collagen mixture because applicants disclosed the collagen mixture as collagen and solvent, page 9, line 14 (col.6, lines 49-57).

The limitations of claims 1-4, 6, and 8-10 are met by US '773.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '362 or US '773, each standing by itself or in view of US 5,716,633 ('633).

The teachings of US '362 and US '773 are discussed above. The references, however, do not teach the gamma radiation is subsequent to UV radiation.

It is within the skill in the art to select the polymerization technique depending on the desired character of the collagen based on the intended use because the nature of collagen is altered by the way of cross-linking, such as strength and color etc. Applicants did not show superior or unexpected results from the exposure of the composition to gamma radiation subsequent to UV radiation. Thus, exposure of the composition to gamma radiation subsequent to UV radiation does not render the claims patentable, absent evidence to the contrary.

US '633 teaches collagen hydrogel for promoting epithelial cell growth during healing process (abstract; col.4, lines 58-59; col.11, lines 25-29). The collagen hydrogel is exposed to gamma radiation and then placed under UV light (col.13, lines 54-59).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide composition comprising irradiated sugar and collagen as disclosed by both of US '362 and US '773, and perform both gamma and UV irradiation as disclosed by US '633, motivated by the teaching of US '633 that the collagen hydrogel produced cross-linked by irradiation promotes epithelial cell growth during

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healing process, with reasonable expectation of having an irradiated composition comprising sugar and collagen mixture that is used successfully in wound healing compositions.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali

ISIS GHALI
PATENT EXAMINER